

k072437

## 510(k) Summary

FEB - 5 2008

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**Introduction** According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

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**Submitter name, address, contact** Roche Diagnostics Corporation  
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Indianapolis, IN 46250  
(317) 521-3544

Contact Person: Kay Taylor

Date Prepared: January 28, 2008

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**Device Name** Proprietary name: 1.) Elecsys® proBNP II Immunoassay  
2.) Elecsys® PreciControl Cardiac II  
3.) Elecsys® proBNP II CalSet

Common name: 1.) proBNP Assay  
2.) PreciControl Cardiac  
1.) proBNP CalSet

Classification name: 1.) Test, Natriuretic Peptide  
2.) Multi-Analyte Controls, All Kinds (Assayed and Unassayed)  
3.) Calibrator, Secondary

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## 510(k) Summary, continued

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- Description**
- 1.) The Elecsys proBNP II Assay is a two step sandwich immunoassay with streptavidin microparticles and electrochemiluminescence detection. Results are determined using a calibration curve that is generated specifically on each instrument by a 2 point calibration and a master curve provided with the reagent bar code.
  - 2.) The Elecsys PreciControl Cardiac II is a lyophilized product consisting of human serum with added CK-MB, Digitoxin (not for use in U.S), Digoxin, Myoglobin, and NT-proBNP 1-76 in two concentration ranges. During manufacture, the analytes are spiked into the matrix at the desired concentration levels.
  - 3.) The Elecsys proBNP II CalSet is a lyophilized product consisting of equine serum with added NT-proBNP 1-76 in two concentration ranges. During manufacture, the analyte is spiked into the matrix at the desired concentration levels.
- Note: The reagent, calibrator, and quality control material are all packaged separately.
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**Intended Use / Indications for Use**

**Elecsys proBNP II:** Immunoassay for the in vitro quantitative determination of N-terminal pro-Brain natriuretic peptide in human serum and plasma. Elecsys proBNP II assay is used as an aid in the diagnosis of individuals suspected of having congestive heart failure. The test is further indicated for the risk stratification of patients with acute coronary syndrome and congestive heart failure. The test may also serve as an aid in the assessment of increased risk of cardiovascular events and mortality in patients at risk for heart failure who have stable coronary artery disease. The electrochemiluminescence immunoassay “ECLIA” is intended for use on Elecsys and **cobas e** immunoassay analyzers.

The **Elecsys PreciControl Cardiac II** is used for quality control of specified immunoassays on the Elecsys and cobas e immunoassay analyzers.

The **Elecsys proBNP II CalSet** is used for calibrating the quantitative Elecsys proBNP II assay on the Elecsys and cobas e immunoassay analyzers.

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## 510(k) Summary, continued

### Substantial equivalence

The Elecsys proBNP II Test System is substantially equivalent to other devices legally marketed in the United States.

- 1.) Elecsys proBNP II Immunoassay is equivalent to the Elecsys proBNP Immunoassay (K051382).
- 2.) Elecsys PreciControl Cardiac II is equivalent to Elecsys PreciControl Cardiac (K032089).
- 3.) Elecsys proBNP II CalSet is equivalent to Elecsys proBNP CalSet (K022516).

### Device Comparison – Immunoassay

The following table compares the Elecsys proBNP II test system with the predicate device (K051382).

Immunoassay		
Feature	Elecsys proBNP II Assay	Elecsys proBNP Assay (K051382) Predicate
Intended Use / Indication for Use	<p>Immunoassay for the <i>in vitro</i> quantitative determination of N-terminal pro-Brain natriuretic peptide in human serum and plasma. The Elecsys proBNP assay is used as an aid in the diagnosis of individuals suspected of having congestive heart failure. The test is further indicated for the risk stratification of patients with acute coronary syndrome and congestive heart failure. The test may also serve as an aid in the assessment of increased risk of cardiovascular events and mortality in patients at risk for heart failure who have stable coronary artery disease.</p> <p>The electrochemiluminescence immunoassay "ECLIA" is intended for use on Elecsys and <b>cobas e</b> immunoassay analyzers.</p>	<p>Same</p> <p>The electrochemiluminescence immunoassay "ECLIA" is intended for use on the Elecsys 1010/2010 and MODULAR ANALYTICS E170 (Elecsys module) immunoassay analyzers.</p>

## 510(k) Summary, continued

<b>Immunoassay</b>		
<b>Feature</b>	<b>Elecsys proBNP II Assay</b>	<b>Elecsys proBNP Assay (K051382) Predicate</b>
Analyzer Platforms	Elecsys 1010 Elecsys 2010 / cobas e 411 MODULAR ANALYTICS E170 (Elecsys module) / cobas e 601	Elecsys 1010 Elecsys 2010 MODULAR ANALYTICS E170 (Elecsys module)
Assay Protocol	Sandwich Principle	Same
Detection Protocol	Electrochemiluminescent	Same
Traceability / Standardization	Standardized against the Elecsys proBNP assay.	Reference standard – purified synthetic NT-proBNP (1-76) in equine serum matrix
Calibration Interval	E170/E2010/ cobas e analyzers <ul style="list-style-type: none"> <li>After 1 month when using the same reagent lot</li> <li>After 7 days when using the same reagent kit</li> </ul> E1010 <ul style="list-style-type: none"> <li>With every reagent kit</li> <li>After 7 days (20-25°C)</li> <li>After 3 days (25-32°C)</li> </ul>	E170/E2010 <ul style="list-style-type: none"> <li>After 1 month (28 days) when using the same reagent lot</li> <li>After 7 days when using the same reagent kit</li> </ul> E1010 <ul style="list-style-type: none"> <li>With every reagent kit</li> <li>After 7 days (20-25°C)</li> <li>After 3 days (25-32°C)</li> </ul>
Sample Type	Human serum and plasma	Same
Reagent Stability	Unopened <ul style="list-style-type: none"> <li>Up to stated expiration date stored at 2-8°C</li> </ul> Opened <ul style="list-style-type: none"> <li>12 weeks at 2-8°</li> <li>8 weeks on E170/cobas e 601</li> <li>8 weeks on E2010/ cobas e 411</li> <li>4 weeks on E1010 (20-25° ambient temp, up to 20 hours opened in total)</li> </ul>	Unopened <ul style="list-style-type: none"> <li>Up to stated expiration date stored at 2-8°C</li> </ul> Opened <ul style="list-style-type: none"> <li>12 weeks at 2-8°</li> <li>8 weeks on E170</li> <li>8 weeks on E2010</li> <li>4 weeks on E1010 (20-25° ambient temp, up to 20 hours opened in total)</li> </ul>
Calibrator	Elecsys proBNP II CalSet	Elecsys proBNP CalSet
Controls	Elecsys PreciControl Cardiac II	Elecsys PreciControl Cardiac
Result Interpretation	125 pg/ml for patients younger than 75 years and 450 pg/ml for patients 75 years and older.	Same

## 510(k) Summary, continued

Immunoassay		
Feature	Elecsys proBNP II Assay	Elecsys proBNP Assay (K051382) Predicate
Instrument	Elecsys 1010, Elecsys 2010, cobas e 411, cobas e 601, and MODULAR analytics E170 family of analyzers	Elecsys 1010 Elecsys 2010 MODULAR ANALYTICS E170 (Elecsys module)
Measuring Range	5-35,000 pg/mL	Same
Precision	<u>E170 and cobas e601 – Within run</u> 1.9% CV @ 64 pg/mL 1.5% CV @ 124 pg/mL 1.3% CV @ 14142 pg/mL 1.8% CV @ 77.0 pg/mL 1.2% CV @ 2105 pg/mL  <u>E170 and cobas e601 – Total</u> 3.1% CV @ 46 pg/mL 2.7% CV @ 125 pg/mL 1.7% CV @ 32930 pg/mL 2.7% CV @ 77.0 pg/mL 2.7% CV @ 2170 pg/mL  <u>E1010/2010 and cobas e 411 – Within run</u> 4.2%CV @ 44.0 pg/mL 2.4%CV @ 126 pg/mL 1.3%CV @ 2410 pg/mL 2.7%CV @ 33606 pg/mL 2.58% CV @ 82.0 pg/mL 1.18% CV @ 2318 pg/mL  <u>E1010/2010 and cobas e411 – Total</u> 4.6%CV @ 44.0 pg/mL 2.6%CV @ 126 pg/mL 1.8%CV @ 2410 pg/mL 3.8%CV @ 33606 pg/mL 2.8% CV @ 82.0 pg/mL 1.6% CV @ 2318 pg/mL	<u>E170 - Within run</u> 0.9% CV @ 474 pg/mL 1.1% CV @ 8005 pg/mL 0.9% CV @ 13682 pg/mL 0.8% CV @ 208 pg/mL 3.0% CV @ 3786 pg/mL  <u>E170 - Total</u> 5.8% CV @ 494 pg/mL 4.1% CV @ 7827 pg/mL 3.7% CV @ 13143 pg/mL 4.5% CV @ 200 pg/mL 3.6% CV @ 4002 pg/mL  <u>E1010/2010 – Within run</u> 2.7% CV @ 175 pg/mL 2.4% CV @ 355 pg/mL 1.9% CV @ 1068 pg/mL 1.8% CV @ 4962 pg/mL 1.8% CV @ 434 pg/mL 1.8% CV @ 6781 pg/mL  <u>E1010/2010 – Total</u> 3.2% CV @ 175 pg/mL 2.9% CV @ 355 pg/mL 2.6% CV @ 1068 pg/mL 2.3% CV @ 4962 pg/mL 2.4% CV @ 434 pg/mL 2.2% CV @ 6781 pg/mL

## 510(k) Summary, continued

Immunoassay, continued		
Feature	Elecsys proBNP II Assay	Elecsys proBNP Assay (K051382) Predicate
Hook Effect	No effect up to 300,000 pg/mL	same
Analytical Sensitivity	5 pg/mL	same
Method Comparison	Elecsys proBNP II (y) compared to Elecsys proBNP (x): linear regression ( $y = 1.0x - 21.74$ ); Passing /Bablok ( $y = 0.98x - 0.31$ )	n.a.
Limit of Blank / Analytical Sensitivity	1.72 pg/mL	5 pg/mL
Limit of Detection	2.83 pg/mL	
Limit of Quantitation (as determined by a functional sensitivity study)	50 pg/mL	< 50 pg/mL
Limitations	<ul style="list-style-type: none"> <li>No interference from bilirubin if less than 25 mg/dL</li> <li>No interference from hemoglobin if less than 1.0 g/dL</li> <li>No interference from intralipids if less than 1500 mg/dL</li> <li>No interference with biotin if less than 30 ng/mL</li> <li>No interference from rheumatoid factor up to 1500 IU/mL</li> <li>In patients receiving high biotin doses &gt; 5 mg/day, sample should not be taken until 8 hours after administration.</li> <li>Rare occurrence of interference from high titers of anti-streptavidin and ruthenium</li> <li>Use in conjunction with patient medical history, clinical exam and other findings</li> </ul>	<ul style="list-style-type: none"> <li>No interference from bilirubin if less than 35 mg/dL</li> <li>No interference from hemoglobin if less than 1.4 g/dL</li> <li>No interference from triglycerides if less than 4000 mg/dL</li> <li>No interference with biotin if less than 30 ng/mL</li> <li>No interference from rheumatoid factor up to 1500 IU/mL</li> <li>In patients receiving high biotin doses &gt; 5 mg/day, sample should not be taken until 8 hours after administration.</li> <li>Rare occurrence of interference from high titers of anti-streptavidin and ruthenium</li> <li>Use in conjunction with patient medical history, clinical exam and other findings</li> </ul>

## 510(k) Summary, continued

**Device Comparison – PreciControl Cardiac II**      The following table compares the Elecsys proBNP II test system with the predicate device (K032089).

<b>PreciControl Comparison</b>		
<b>Characteristic</b>	<b>Elecsys PreciControl Cardiac II</b>	<b>Elecsys PreciControl Cardiac (K032089) Predicate</b>
Intended Use	Used for quality control of specified immunoassays on the Elecsys and cobas e immunoassay analyzers.	Used for quality control of the Elecsys CK-MB, Digoxin, Myoglobin, and NT-proBNP immunoassays on the Elecsys immunoassay systems.
Levels	Two	same
Format	Lyophilized, based on human serum	same
Analyte Concentration	CK-MB: approx. 5 and 50 ng/ml Digitoxin: approx. 17 and 38 ng/mL (not for use in U.S.) Digoxin: approx. 1.2 and 3 ng/ml Myoglobin: approx. 80 and 1000 ng/ml NT-proBNP: approx. 0.15 and 5 ng/ml	CK-MB: approx. 5 and 50 ng/ml Digoxin: approx. 1.2 and 3 ng/ml Myoglobin: approx. 80 and 1000 ng/ml NT-proBNP: approx. 0.15 and 5 ng/ml
Stability	Unopened: store at 2 – 8°C up to expiration date  Reconstituted: 3 hrs at 20 – 25°C (on analyzer) 3 days at 2 – 8°C 3 months at -20°C (freeze only once) After thawing – use only once	same
Handling	Dissolve carefully the contents of one bottle by adding exactly 2.0 mL of distilled water and allow stand closed for 15 minutes to reconstitute. Mix carefully, avoiding the formation of foam.	same

## 510(k) Summary, continued

**Device Comparison – CalSet**      The following table compares the Elecsys proBNP II test system with the predicate device (K032089).

<b>CalSet Comparison</b>		
<b>Characteristic</b>	<b>Elecsys proBNP II CalSet</b>	<b>Elecsys proBNP CalSet (K022516) Predicate</b>
Intended Use	Used for calibrating the quantitative Elecsys proBNP II assay on Elecsys and cobas e immunoassay analyzers.	Used for calibrating the quantitative Elecsys proBNP assay on Elecsys 1010/2010 and MODULAR ANALYTICS E170 immunoassay systems.
Levels	Two	same
Format	Lyophilized, based on equine serum	same
Stability	Unopened: <ul style="list-style-type: none"> <li>• Store at 2 – 8°C until expiration date.</li> </ul> Reconstituted: <ul style="list-style-type: none"> <li>• 2 – 8°C: 2 weeks</li> <li>• -20°C: 3 months (freeze only once)</li> <li>• On Elecsys 1010/2010 and cobas e411 analyzers at 20 – 25°C: up to 5 hours</li> <li>• On MODULAR ANALYTICS E170 and cobas e601 analyzers: use only once</li> </ul>	Unopened: <ul style="list-style-type: none"> <li>• Store at 2 – 8°C until expiration date.</li> </ul> Reconstituted: <ul style="list-style-type: none"> <li>• 2 – 8°C: 2 weeks</li> <li>• -20°C: 3 months (freeze only once)</li> <li>• On Elecsys 1010/2010 analyzers at 20 – 25°C: up to 5 hours</li> <li>• On MODULAR ANALYTICS E170: use only once</li> </ul>
Handling	Dissolve contents of one bottle by adding exactly 1.0 mL of distilled water and allow to stand closed for 15 minutes to reconstitute. Mix carefully, avoiding the formation of foam.	same





DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FEB - 5 2008

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Roche Diagnostics Inc.  
c/o Ms. Kay A. Taylor MT (ASCP)  
Regulatory Affairs Principal  
9115 Hague Road  
PO Box 50457  
Indianapolis, IN 46250

Re: k072437  
Trade/Device Name: Elecsys proBNP II Immunoassay  
Regulation Number: 21 CFR§ 862.1117  
Regulation Name: B-Type Natriuretic Peptide  
Regulatory Class: Class II  
Product Code: NBC, JJY, JIT  
Dated: January 29, 2008  
Received: January 30, 2008

Dear Ms. Taylor:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink that reads "Jean M. Cooper, M.S., D.V.M.".

Jean M. Cooper, M.S., D.V.M.

Director

Division of Chemistry and Toxicology

Office of *In Vitro* Diagnostic Device

Evaluation and Safety

Center for Devices and

Radiological Health

Enclosure

## Indications for Use – Elecsys proBNP II Immunoassay

510(k) Number (if known):

Device Name: **Elecsys proBNP II Immunoassay**

Indication For Use:

Immunoassay for the in vitro quantitative determination of N-terminal pro-Brain natriuretic peptide in human serum and plasma. Elecsys proBNP II assay is used as an aid in the diagnosis of individuals suspected of having congestive heart failure. The test is further indicated for the risk stratification of patients with acute coronary syndrome and congestive heart failure. The test may also serve as an aid in the assessment of increased risk of cardiovascular events and mortality in patients at risk for heart failure who have stable coronary artery disease.

The electrochemiluminescence immunoassay “ECLIA” is intended for use on Elecsys and cobas e immunoassay analyzers.

Prescription Use XXX  
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use \_\_\_\_  
(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C Benson  
Division Sign-Off  
Office of In Vitro Diagnostic Device  
Evaluation and Safety

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## Indication for Use – Elecsys PreciControl Cardiac II

510(k) Number (if known):

Device Name: **Elecsys PreciControl Cardiac II**

Indication For Use:

The Elecsys PreciControl Cardiac II is used for quality control of specified immunoassays on the Elecsys and cobas e immunoassay analyzers.

Prescription Use XXX  
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use \_\_\_\_  
(21 CFR Part 801 Subpart C)

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Evaluation and Safety

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## Indication for Use - Elecsys proBNP II CalSet

510(k) Number (if known):

Device Name: **Elecsys proBNP II CalSet**

Indication For Use:

The Elecsys proBNP II CalSet is used for calibrating the quantitative Elecsys proBNP II assay on the Elecsys and cobas e immunoassay analyzers.

Prescription Use XXX  
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use \_\_\_\_  
(21 CFR Part 801 Subpart C)

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